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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,543	10/30/2003	Jianping Cai	21454	7592
151	7590	02/01/2006		
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			EXAMINER MCKENZIE, THOMAS C	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 02/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,543

Applicant(s)

CAI ET AL.

Examiner

Thomas McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 34-43 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-30 and 40 is/are allowed.
- 6) ☒ Claim(s) 31 and 34-39 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to amendments filed on 11/21/05. Applicant has amended claims 18, 20, 21, 27, 29, 31, 34, 36, and 37. Applicant has canceled claim 33. Claims 30-32 and 34-39 were previously rejected. Claims 1-32 and 34-39 were designated as containing allowable subject matter.

Response to Amendments and Arguments

2. Applicants' correction of a computer glitch concerning the Greek symbol λ overcomes the objection made in point #7 of the previous office action. This λ nomenclature is a standard method of indicating hypervalent heteroatoms and does not introduce new matter. Applicants' correction of a typo in claim 37 overcomes the objection made in point #8 of that action. Applicants point to Greene (Protecting Groups in Organic Synthesis) and to *Ex parte Matzinger* (BPAI Appeal No. 2003-2146) as evidence that the structures of "an optionally protected NH_2 group" are known in the art of organic chemistry and evidence that the Examiner is unlikely to prevail with his indefiniteness rejection. Thus, the indefiniteness rejection made in point #9 of that action is withdrawn.

Applicants' cancellation of claim 33 renders moot the indefiniteness rejection made in point #12 of that action. Applicants' correction of amine to ammonia overcomes the indefiniteness rejection made in point #13. Applicants'

correction of leaving group L to protecting group overcomes the indefiniteness rejection made in point #14 of that action.

Election/Restrictions

3. Claims 41-43 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 32 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the line immediately above formula (III) of claim 31, Applicants' have the limitation "general formula". The word "general" implies more than one formula is being claims. The Examiner suggests removing the word "general".

Applicants removed the word "general" from the second line of claim 31 but neglected to correct the second occurrence of the word.

5. Claim 31 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the second line above formula (III) in claim 31, Applicants have the limitation, "L signifies a leaving group". In the

sentence bridging pages 18 to 19 of the specification, Applicants have an open definition of the term. In the last three lines on page 19, there is a different definition of the concept of "leaving group". Which one is intended? In addition to the radicals listed in these two lists, what else is being claimed? As explained by A D McNaught & A Wilkinson, in "IUPAC Compendium of Chemical Terminology, 2nd Ed", "[t]he term [leaving group] has meaning only in relation to a specified reaction." This means that a universal list of such groups is not possible and the leaving groups in molecule (II) must differ from the leaving groups in molecule (V). The Examiner suggests using the specific leaving groups listed in claim 32.

6. Claims 34-39 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the penultimate line of the claim, Applicants have the limitation "a leaving group". This was discussed above. The Examiner suggests using the definition in claim 32 for leaving group L and the specific leaving groups listed in the last two lines of page 19 for L'.

Applicants make three arguments concerning these two rejections. Applicants argue that "leaving group" is a commonly used term in organic synthesis, that many US Patents have issued with such terms in the claims, and

that a Goggle search reveals many uses of the term in the open chemical literature. This is not persuasive.

Concerning the first argument, while the concept of leaving group is well known and taught in sophomore organic chemistry, there is no standard list of such groups like there is with "protecting group". The reasons for the lack of any agreed upon list of leaving groups was provided by A D McNaught & A Wilkinson, in "IUPAC Compendium of Chemical Terminology, 2nd Ed". Whether a radical will function as a leaving group will depend upon the substrate undergoing the reaction, the nucleophile doing the reacting, and the specific conditions of the reaction. A leaving group in one reaction will not necessarily be a leaving group in another reaction. For example, Applicants' leaving group L is involved in a nucleophilic aromatic substitution reaction with ammonia as the nucleophile. Applicants leaving group L' is involved in an S_n^2 type nucleophilic aliphatic substitution reaction with a heterocyclic amine as the nucleophile. Applicants themselves recognize this difference and give a different list of preferred leaving groups for the two different reactions. Fluorine is listed as a possible value for L but it is not listed for L'. Is fluorine included within the metes and bounds of the definition of L'?

Concerning the use of "leaving group" in other patent claims, the indefiniteness remains despite what was allowed in another case. The U.S. Court of Customs and Patent Appeals wrote *In re Giolito* 188 USPQ 645: "We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others. See *In re Margaroli*, 50 CCPA 1400, 318 F.2d 348, 138 USPQ 158 (1963); *In re Wright*, 45 CCPA 1005, 256 F.2d 583, 118 USPQ 287 (1958); *In re Launder*, 41 CCPA 887, 212 F.2d 603, 101 USPQ 391 (1954)".

Concerning the wide usage of the phrase in the chemical literature, while the concept may be well known, these cited references do nothing to clarify what radicals are included within the limitation. The lecture notes from the University of Maine use the term only in connection with the nucleophilic aliphatic substitution reaction, *i.e.* the type of reaction in which Applicants' variable L' is involved. The only leaving group mentioned in this reference is iodide, which does nothing to clarify what additional groups Applicants are claiming in addition to those listed in the specification. Dorwald (Side Reactions in Organic Synthesis) apparently has a section titled "structure of the leaving group" but since this book is not readily available and was not supplied to the Examiner, there is no way to

determine what other leaving groups are mentioned in addition to those listed in the specification.

Allowable Subject Matter


7. Claims 1-30 and 40 are allowed. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 31 and 34-39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

10. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


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